UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

BARBARA HEINRICH and GREGORY HEINRICH,

Plaintiffs

v.

ETHICON, INC.; ETHICON LLC; and JOHNSON & JOHNSON,

Defendants

Case No.: 2:20-cv-00166-APG-VCF

Order Granting in Part Defendants' Motion in Limine No. 6

[ECF No. 134]

This case is one of many thousands of cases that were joined in multidistrict litigation (MDL) in the United States District Court for the Southern District of West Virginia. The case was transferred to this court for trial in January 2020. ECF No. 69.

The defendants filed a motion *in limine* seeking to exclude from trial three categories of evidence: (1) third-party comments to the Food and Drug Administration (FDA) for the 2011 FDA Advisory Committee meeting, (2) the 2012 FDA 522 Order,[1] and (3) the FDA's 2014, 2016, and 2019 actions concerning classification of transvaginal prolapse mesh.

A. Third-Party Comments

The defendants contend that comments third parties submitted to the FDA are hearsay and admitting them would give the jury the false impression that the comments' views were adopted by the FDA. The plaintiffs respond that the defendants have not adequately identified what evidence they seek to exclude and that there may be reasons why some third-party comments would be admissible, such as for impeachment or to show defendants' notice.

[1] Although the defendants refer to "orders," they attach only one to their motion. I therefore address only that order.

The defendants have not identified the evidence they seek to exclude except by category. The defendants do not attach the comments to their motion. The plaintiffs do not dispute that, as a general matter, third party comments to the FDA would be hearsay. Although the plaintiffs argue there may be non-hearsay uses for some of the comments, they do not provide the comments they may potentially seek to use at trial.

Because neither side has presented me with the evidence at issue, the parties have left me unable to rule except to state as a general matter that third-party comments to the FDA are inadmissible hearsay unless the party offering the comments can demonstrate they fall within an exception to the hearsay rule or are being offered for a non-hearsay purpose. Fed. R. Evid. 801-07. To that extent, the defendants' motion *in limine* is granted as to the third-party comments.

B. 2012 FDA 522 Order

In January 2012, the FDA sent Ethicon a letter instructing it to collect and provide post-market surveillance data concerning the TVT-S under section 522 of the Federal Food, Drug, and Cosmetic Act. ECF No. 134-2. The FDA ordered Ethicon to conduct a post-market study to answer several questions, including about the rate of effectiveness and adverse events associated with the TVT-S compared to other mesh slings, as well as the quality of life of women receiving the TVT-S versus other mesh products. *Id.* The defendants apparently decided not to conduct the study and instead chose to no longer offer TVT-S for sale as reflected in the June 2012 letter to physicians advising them that the TVT-S would be discontinued. ECF No. 131-1.

The defendants contend this letter (1) is irrelevant because it was issued years after Heinrich was implanted with the TVT-S, (2) will not aid the jury in determining whether the device was dangerous or that Ethicon knew of any danger prior to Heinrich's implantation, and (3) will require the defendants to explain what the FDA letter was meant to convey. The

plaintiffs respond that this evidence is relevant to show that the plaintiffs could not have discovered their claims earlier where the defendants either could not or would not answer the questions the FDA posed. The plaintiffs contend that it was only after the FDA issued the 2012 order that Barbara Heinrich's doctor told her that the mesh material may be defective.

The January 2012 letter is relevant to the first-phase trial in this case because it goes to whether a reasonably diligent plaintiff could or should have discovered her claims. The defendants either could not or would not answer the questions the FDA posed even though they would have had more information about the rates of effectiveness and adverse events than would a member of the public. If the defendants did not know as late as 2012 whether the TVT-S was less effective and caused more adverse reactions, or they knew and chose not to disclose that information, that may impact the jury's determination of whether the plaintiffs could or should have discovered earlier that the TVT-S was the cause of their injuries as opposed to typical complications from stress urinary incontinence treatments.

Because the first-phase jury may determine that the plaintiffs' claims are untimely, I defer ruling on whether this evidence is admissible for purposes of liability or damages. I therefore deny this portion of the defendants' motion, without prejudice to renew it if the first-phase jury finds the plaintiffs' claims are timely.

C. FDA's 2014, 2016, and 2019 Actions

In May 2014, the FDA published two proposed orders recommending that transvaginal mesh products be reclassified as Class III medical devices. In January 2016, the FDA issued a final order reclassifying the products. And in 2019, the FDA ordered the remaining manufacturers of these products to remove them from the market.

The defendants argue this evidence is irrelevant because the TVT-S is not a transvaginal mesh product and letting the jury hear that a different type of product was subject to premarket approval and later removed from the market would be unfairly prejudicial. The plaintiffs respond by not opposing exclusion of this evidence if Timothy Ulatowski is excluded as an expert. But the plaintiffs assert that they may seek to introduce this evidence if the defendants open the door regarding the safety of Prolene mesh in non-TVT products.

I grant the defendants' motion to exclude this evidence as unopposed because I have excluded Timothy Ulatowski as an expert in this case. ECF No. 160. To the extent the plaintiffs believe the defendants have opened the door on this topic at trial, they should advise the defendants and the court before seeking to introduce this evidence.

D. Conclusion

I THEREFORE ORDER that the defendants' motion *in limine* No. 6 **(ECF No. 134) is GRANTED in part** as set forth above.

DATED this 1st day of November, 2021.

ANDREW P. GORDON
UNITED STATES DISTRICT JUDGE